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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,370	03/15/2001	Yukino Owaki	204395US0XPC	7568

22850 7590 02/20/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,370

Applicant(s)

OWAKI ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-7 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Extension of Time and Amendment B received on November 19, 2002 are acknowledged. Claims 1-19 are included in the prosecution of this application. Claims 8-9 are cancelled.

#### ***Information Disclosure Statement***

The information disclosure statement filed June 4, 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-7, 10-12, 14-15, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al (6,177,098) by itself or in view of Kubo et al (5,827,528).**

Kawaji et al teaches a percutaneous patch containing 20% SIS block copolymer, 50% rosin resin, 18% polybutene, and 1% liquid paraffin, 1% dibutylhydroxytoluene (antioxidant), and 2% lidocaine. The mixture is applied to a polyester base (thickness of 75 microns) (example 3). Kawaji teaches the softeners for the mixture may be liquid paraffin or liquid rubber (col.4, lines 65-67). The reference teaches adjusting the amount of softeners and oils to yield the desired properties of the adhesive base (col. 4, lines 59-60).

Kawaji does not teach instant 5% liquid paraffin in the adhesive base. Kawaji does not teach instant hydrocarbon resin.

Kubo et al teaches a medical adhesive composition. The composition contains a thermoplastic elastomer such as SIS, butyl rubber, a softener, and tackifier. Kubo teaches the tackifier may be a hydrocarbon resin, petroleum resin, or a terpene-phenol resin (col. 5, lines 15-28). Further, Kubo teaches the manipulation of softeners in the composition wherein the softener lowers the hardness of the elastomer. If the hardness is too high then the adhesive composition will not fit well on the skin (col. 6, lines 17-37). Note also embodiment 1.

In the absence of showing criticality of the instant 5% of liquid paraffin, it is deemed obvious to one of ordinary skill in the art to manipulate the amount of softener in the adhesive base. One would be motivated to do so to yield the desired toughness and flexibility to the adhesive mixture. Further, Kawaji teaches the use of either liquid paraffin and liquid rubber to soften the mixture; therefore in the absence of showing otherwise, it is the examiner's position that the two mixtures would be similar since the

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example contains both as seen in instant claims except that Kawaji uses more of the liquid rubber to soften the mixture. Lastly, in the absence of showing the criticality of alicyclic hydrocarbon resin and rosin resin, it is deemed obvious to use a suitable resin since both accomplish the function of acting as a tackifier, both are hydrocarbon resins, and are contained in similar amounts.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kawaji and Kubo since both teach medical adhesive compositions. One would be motivated to do so since Kubo teaches the equivalency of the instant resin and rosin resin (terpene resins) and teaches the motivation of manipulating the amounts of softener in the adhesive composition.

\*Note claims 2-5 and 10 have functional limitations on the product claims; therefore they do not hold patentable weight since the functional limitation does not have a structural limitation on the product itself.

**Claim 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaji et al (6,177,098) by itself or in view of Kubo et al (5,827,528), in further view of JP 07233054.**

As set forth above, the references teach transdermal preparations.

The references do not teach the use of 5% of lidocaine.

JP teaches the instant amount of lidocaine to alleviate pain in a pressure sensitive adhesive base (SIS copolymer) (Note abstract).

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the amount of active agent in the adhesive composition

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depending on the condition to be treated. One would be motivated to do so since JP teaches that lidocaine in the instant amount treats pain. Further, one would be motivated to combine the references with the expectation of similar results since JP also teaches a similar adhesive base. Lastly, in the absence of showing the criticality and unexpected results of the instant percentages in claim 19, it is deemed obvious to optimize these ranges according to the teachings of the prior art since the prior art provides the guidance and teaches overlapping/similar ranges.

**Claims 1-5, 10-14, and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al (6,139,866).**

Chono et al teach a tape formulation. Chono teaches the active component as fentanyl itself (base form) or its salt in the amount of .05-20%. The adhesive base contains 16.2% SIS block copolymer, 6.9% PIB, 28.9% liquid paraffin, 41.5% resin, and .5% BHT (Note examples). The mixture is placed on a backing layer. Suitable tackifiers resins taught are rosin, polyterpene resins, and Arcon (instant resin) (col. 3, lines 45-55).

Chono et al does not exemplify the instant resin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an alicyclic hydrocarbon resin as the tackifier in the adhesive base. One would be motivated to do so since Chono et al teaches several tackifiers, including instant tackifiers, are suitable for the adhesive base.

Note that although the reference teaches a salt form of the drug, Chono clearly teaches that either the base form or the salt form are suitable in the composition; therefore Chono reads on instant invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for



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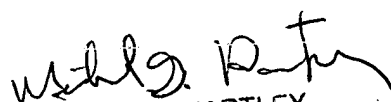
the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

SSG



January 30, 2003



MICHAEL G. HARTLEY  
PRIMARY EXAMINER